

REMARKS

Claims 1 through 15 are currently pending. Applicant respectfully requests that paragraph [0053] be deleted from the Specification.

Specification

Applicants respectfully request that paragraph [0053] be deleted from the Specification since Graph 1 was not included in the present application.

Rejection under 35 U.S.C. § 103

Claims 1 through 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Aoi et al. (hereinafter "Aoi") in view of Gans et al. (hereinafter "Gans") and Furia.

Specifically, the Office Action states that Aoi teaches an enteral complete solution which may include parabens, benzoic acid salts and sorbic acid salts. Aoi, however, is silent in teaching the particular type of amount of parabens, salts of benzoic acid, and salts of sorbic acid. Additionally, the Office Action states that Gans teaches compositions that prevent nutritional deficiency and the use of one or more preservatives from 0.4 to 1%, such as potassium sorbate, sodium benzoate, methyl and propyl parabens.

Applicants respectfully submit that this rejection is improper because a *prima facie* case of obviousness has not been established. The three elements of a *prima facie* case of obviousness are: 1) some suggestion or motivation to modify the reference or combine the teachings; 2) a reasonable expectation of success and 3) the prior art references must teach or suggest all the claim limitations. It is respectfully submitted that not all of these elements have been established by Aoi in view of Gans and Furia.

First, there must be a suggestion or motivation to modify Aoi in view of Gans. Although both Aoi and Gans discuss nutritional compositions; the nutritional compositions in each disclosure are not comparable. Independent Claim 1 of the present invention expressly requires that the composition comprise an enteral complete feeding solution. As stated in paragraph 17 of the Specification, "A complete feeding tube diet typically includes vitamins, minerals, trace elements as well as nitrogen, carbohydrate and fatty acid sources in a liquid form so that it can be used as the sole source of nutrition supply essentially all the required daily amounts of vitamins, minerals, carbohydrates, fatty acids and the like." Thus, an important aspect of an enteral complete feeding solution is the necessity of having all of the required micro and macronutrients required by a person.

The nutritional compositions disclosed in Gans are not complete feeding solutions. Gans teaches or suggests solutions that expressly exclude fat which is a macronutrient required for a complete feeding solution. In column 2, lines 47 through 58, Gans distinguishes its disclosed nutritional compositions from those of the prior art by the very fact that they lack triglycerides.

Furthermore, in Column 3, lines 15 through 20, *Gans* characterizes the nutritional compositions i as "an orally-ingestible, predigested protein composition . . . containing all of the essential amino acids and being free of undesirable triglycerides and fats." Thus, one of ordinary skill in the art would not be motivated to combine *Aoi* with *Gans* since *Aoi* does focus on a nutritionally complete feeding solution whereas *Gans* does not. *Furia* also fails to teach or suggest the use of parabens in combination with salts of benzoic and sorbic acids in a nutritionally complete feeding solution. Thus, there is no suggestion or motivation to combine *Furia* with *Aoi*.

Second, there is no expectation of success from the combination of *Aoi* in view of *Gans* and *Furia*. The Applicants have surprisingly discovered that an alkyl paraben when used in combination with the salts of benzoic and sorbic acids results in an enhanced synergism when functioning as a preservative. As shown in Example 4 of the Specification, the Applicants have found that the inhibitory synergism resulting from a combination of propyl paraben, sodium benzoate and potassium sorbate was greater than any of them singly for *Candida albicans*, *Enterobacter cloacae*, *Staphylococcus aureus*, and *Lactobacillus delbrueckii*.

None of *Aoi*, *Gans* or *Furia* provide any teaching or suggestion of the synergistic benefit of using a combination of an alkyl paraben with the salts of benzoic and sorbic acids. *Aoi* simply provides a laundry list of preservatives that can be used in the invention. Although *Gans* does show a combination of methyl paraben, propyl paraben with sodium benzoate and potassium sorbate, there is no teaching or suggestion of a synergistic benefit of these preservatives in combination when used in a nutritionally complete feeding solution. *Furia*, like *Gans*, also provides no teaching or suggestion of a synergistic benefit of these preservatives in a nutritionally complete feeding solution.

Thus, because there is no motivation to combine *Aoi*, *Gans* and *Furia*, and because there's no reasonable expectation of success, then the Examiner has not set forth a *prima facie* case of obviousness thus rendering this rejection improper. The Applicants respectfully request that this rejection be withdrawn.

Claims 13 through 15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Gans* in view of *Aoi*. Similar to the prior discussion for Claims 1 through 12, Applicants respectfully submit that a *prima facie* case of obviousness has also not been established. In this rejection, the Examiner recognizes that *Gans* does not teach a complete solution, and uses *Aoi* to provide the teaching. However, the Applicants respectfully submit that there is no suggestion or motivation to combine *Gans* with *Aoi*. A nutritionally complete solution is vastly different from an orally-ingestible, predigested protein composition (as stated in *Gans*). Formulation chemistry is an unpredictable art. Nutritionally complete feeding solutions have more categories of ingredients than that of the compositions disclosed in *Gans*. For example, nutritionally complete feeding solutions also include fatty acid sources, vitamins, minerals and trace elements. Thus, Applicants respectfully submits there is no motivation or suggestion to combine *Gans* with *Aoi*

since the nutritional compositions taught or suggested in each reference is different from each other. Hence, Applicants respectfully request that this rejection be withdrawn.

Thus, in view of the foregoing arguments, Applicants respectfully request reconsideration of the present application. If a telephone interview would be of assistance in advancing the prosecution of this application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

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